

Application No. 08/959,125
Response to Final Action

REMARKS

Claims 5 and 15 are amended in response to the rejections under 35 U.S.C. 112, and only for that purpose. These amendments are not submitted to present any new issue or should not require further search.

Claims 2-5, 14 and 15 remain, with no claim previously allowed.

Entry of the foregoing amendments at this time is proper. Those amendments reduce the number of issues remaining in this application and thus place the application in better condition for appeal. Furthermore, as the applicant points out below, the claims are patentable over the art of record and so entry of this amendment will place those claims in better condition for allowance.

Considering the 35 U.S.C. 112 rejection, Claim 15 was rejected under the first paragraph of 35 U.S.C. 112, in view of the limitation "uniform distribution in the matrix". That limitation is deleted from Claim 15. Accordingly, the amended claim avoids that basis for rejection.

Claim 15 also is amended to claim a range of 5-30 wt% for the contents of the polymer beads, as suggested by the Examiner, thereby overcoming the rejection of "more than about 30%".

In view of the amendments to Claim 15, the limitation on the polymer content in Claim 5 becomes unnecessary and, therefore, is deleted by the present amendment to that claim.

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Summarizing the foregoing, the claims are believed to define only subject matter described in the specification as required by 35 U.S.C. 112, first paragraph.

Turning to the art rejections, Claims 2-5, 14 and 15 stand rejected as anticipated by *Koyama* (4,430,436), "Terahima" (presumably *Terashima* (4,839,278)), or EP 162,302. The applicant respectfully traverses those rejections.

The Examiner asserts that EP teaches, on page 2, lines 30+, indistinguishable polymer wt percentages. However, on page 2, lines 30+ of EP there is no disclosure about the content of the polymer wt%. If the Examiner intended to point out the description in page 9 of EP, the content of the polymer beads is not disclosed therein. In fact, the content of the polymer beads recited in Claim 15 and the claims dependent therefrom is different from the content of the polymer disclosed in EP. Given these substantial differences between the EP disclosure and the combinations of elements recited in the claims, the applicant respectfully submits that the rejection as being "clearly anticipated" by EP is untenable and should be withdrawn.

With respect to the remaining two applied references, the Examiner has stated that the Office would take the position that the selection of polymer concentration would have been obvious as optimization of a result effective variable. Understanding that rejection as a *de facto* rejection based on 35 U.S.C. 103 (obviousness) instead of the stated anticipation rejection, the applicant notes that all the analytical elements described in columns 2 and 3 of *Koyama* have particulate structures. In contradistinction, in the test device of the present invention, the content of the polymer beads is 5 to 30 wt% of the total wt of the single reagent layer. This low content is not disclosed nor suggested by *Koyama*. At the low content, the polymer beads are retained in the matrix and cannot be a material which constitutes the particulate structure. In the present invention, no particulate structure is substantially formed from the polymer beads. The test device of the present invention thus is

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not anticipated by *Koyama* and would not have been obvious based on the teachings of that reference.

In addition, the test device disclosed and claimed by the applicant is believed to be patentable in view of the unexpected advantage as discussed below.

When the light reflective particles are directly contained in the reagent layer, there is the following problem in practical use as described on page 2, line 25 to page 4, line 1 of the present specification. Conventionally, in this kind of dry measuring test device for determining a substance to be measured in a liquid sample through the coloring reaction between the substance to be measured and the reagent, in order to enhance measurement accuracy, an attempt was made to have the light reflective particles directly contained in the reagent layer and have the reagent for coloring contained therein as well. However, if a large amount of light reflective particles is contained to improve the measurement accuracy, the reagent layer becomes so dense that a liquid sample can hardly penetrate and develop, and it takes a long time until the amount of the coloring matter generated by the reaction with the reagent becomes sufficiently measurable. Thus, this is a problem in practical use. Further, it is disadvantageous in that the measurement accuracy may possibly be lowered due to dryness if the measuring time is prolonged as described above.

This problem is solved, according to the present invention, by allowing the light reflective particles to be embedded in polymer beads. The way of using the polymer beads and the advantage thereof are not believed to be anticipated by *Koyama*, which uses polymer beads to construct the particulate structure. *Terashima* is silent about the use of polymer beads. As discussed above, the embedding of light reflective particles in polymer beads is advantageous. The advantages of embedding light reflective particles in polymer beads are clearly evidenced by Example 1 and Comparative Example 1 in the present specification, and are not believed to be anticipated by or taught by *Terashima*. In addition,

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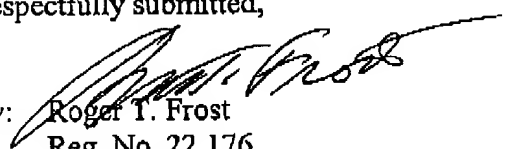
Terashima lacks any motivation for one skilled in the art to embed light reflective particles in polymer beads. In the absence of any such motivation, one skilled in the art could not determine the particular range of polymer beads to be incorporated into the reagent layer and the suitable amount of polymer beads to be incorporated into a reagent layer.

EP also is silent about the use of the polymer beads, as mentioned above.

Summarizing the foregoing, the applicant respectfully requests the Examiner to reconsider and withdrawn the art rejections, and to pass this application to issue.

The foregoing is submitted as a complete response to the Office action identified above. The applicant respectfully solicits a Notice of Allowance for this application.

Respectfully submitted,

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MARKED-UP VERSION OF AMENDMENTS

In the Claims:

Claims are rewritten as follows:

5. (Amended) The dry measuring test device as claimed in Claim [6] 15, wherein the light reflective particles are contained in an amount of 10 to 70 w/v % based on the total content of the polymer beads[, and the polymer beads are contained in an amount of 5 to 80 wt% based on the total weight of the reagent layer].

15. (Amended) A dry measuring test device for detecting a substance in a liquid sample by measuring the degree of reaction between the substance to be measured and a chromogenic reagent in units of reflectance of light, comprising a single reagent layer comprising a reagent containing a chromogen, polymer beads embedding light reflective particles, and a matrix comprising a hydrophilic high molecular substance and which retains said reagent and said polymer beads, wherein the content of the polymer beads is [not more than about] 5 to 30 wt % of the total weight of the single reagent layer[, and wherein said polymer beads are uniformly distributed in the matrix].